

23. A method for improving the absorption of calcium in a mammal comprising the steps of enterally administering to the mammal requiring increased calcium absorption a nutritional composition comprising one or more *Lactobacillus* bacteria.

Please cancel Claims 15 and 20 without prejudice or disclaimer.

REMARKS

This Amendment is submitted in response to the Office Action mailed on May 30, 2002. The Office Action rejects Claims 11-15, 20 and 26 under 35 U.S.C. § 112 and Claims 11-26 under 35 U.S.C. § 102 and 103. In response, Claims 11, 14, 19, and 23 have been amended and Claims 15 and 20 cancelled. Applicants respectfully submit that in view of the Amendment that the rejections have either been overcome or are not proper for the following reasons.

Claims 11-15, 20 and 26 stand rejected under 35 U.S.C. § 112. In part, the claims stand rejected due to the use of the words, in Claim 11, treatment and treating. Claim 11 has been amended to delete the word "treating" and Applicants respectfully submit that as amended the claim is no longer indefinite and respectfully request that the rejection be withdrawn.

Claims 14 and 26 stand rejected under 35 U.S.C. § 112 in view of the recitation "cfu/ml" because the claim fails to set forth whether or not a solid or liquid is provided. Applicants have amended the claims so that it is clear that a liquid composition is referred to in these claims. Applicants respectfully submit that this 35 U.S.C. § 112 rejection has been overcome.

With respect to Claims 15 and 20, these claims have been canceled therefore the 35 U.S.C. § 112 rejection is moot with respect to these claims.

For the foregoing reasons, Applicants submit that the 35 U.S.C. § 112 rejections have been overcome and should be withdrawn.

Claims 11-13 and 15-26 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,578,302 ('302 patent) and Claims 11-26 also stand rejected as being anticipated by U.S. Patent No. 5,494,664 ('664 patent). Applicants respectfully submit that these rejections are not proper. As amended, each of the claims relates to a method of treatment or prophylaxis of calcium deficiencies in a mammal at risk of or having same. Applicants note that support for the Amendment can be found, *inter alia*, in Example No. 1 of Applicants' patent application. Neither the '302 nor the '664 patent discloses such a method.

Each of the '302 and '664 patents relates to general health benefits. Neither of these references discloses mineral absorption in general, let alone calcium absorption in particular. In fact, Applicants note for the record that the claimed health benefits in each of the '302 and '664 patent are not linked to minerals at all but, to an anti-*Helicobacter pylori* effect in the '302 patent and a more general anti-pathogen effect of certain species of *Bifidobacteria* in the '664 patent. Therefore, these references disclose a totally different origin, purpose and mechanism (the displacement of pathogens) and neither disclose nor suggest calcium absorption.

Furthermore, each of the rejected claims are now limited to administering to a mammal requiring increased calcium absorption the composition or diet. As noted in the specification, there are a variety of reasons why a mammal would require increased mineral absorption, e.g., pregnancy or old age. In contrast to the claimed invention, the '664 patent is particularly directed to mammals requiring an antidiarrhoeic (see column 1, lines 35-46) and the '302 patent to patients requiring an antiulcer agent (see column 1, lines 35-44).

Thus, neither of the references inherently discloses the claimed invention as neither reference discloses the claimed patient population. Therefore, as amended, the claims are clearly not anticipated by either of the cited references and accordingly Applicants respectfully request that the anticipation rejection be withdrawn.

Claims 11-26 stand rejected under 35 U.S.C. § 103 as being unpatentable over the '302 patent or the '664 patent taken with *Yaeshima*, *Yoshida*, and *Sellars*. Applicants respectfully submit that the obviousness rejection is not proper for the following reasons.

First, Applicants note that the '302 and '664 patents fail to disclose the claimed invention for the reasons noted above. Moreover, *Yaeshima*, *Yoshida*, and *Sellars* do not remedy the deficiencies of the '302 and '664 patents.

Sellars fails to disclose or suggest the claimed invention. *Sellars* is completely silent as to the increased rate of mineral absorption of any specific mineral. Each of the claims of the present invention is limited to the absorption of calcium.

Further, in *Sellars*, it appears that the presence of a fermented dairy product is necessary. For example, *Sellars* states "there are a number of reports which suggest that when fermented dairy products containing lactobacilli are consumed, the bioavailability for mineral absorption is increased." See page 102. Therefore, it is not clear whether or not lactobacilli or the fermented,

acidified milk is responsible for any increase in mineral absorption. In fact, *Sellars* mentions that "minute quantities of lactic acid influences the rate of absorbed minerals." See page 102.

Therefore, *Sellars* suggests to one skilled in the art that it is sufficient to consume lactic acid of a fermented dairy product to achieve increased mineral absorption. Thus, *Sellars* appears to suggest that the causative agent is lactic acid. Therefore, one skilled in the art would not be motivated to use the claimed lactobacillus bacteria of Applicants' claimed invention.

With respect to *Yoshida*, Applicants believe that when the document is taken as a whole, it teaches away from the claimed invention. In *Yoshida*, mice devoid of any intestinal flora (ex-germ-free mice) were given (a) minerals, and some of the mice (b) were furthermore inoculated with intestinal bacteria. The result was that the mice that were germ-free at the beginning and then became inoculated (the gnotobiotic mice) suffered no deleterious effect on the apparent absorption. In other words, no effect was found. Therefore, *Yoshida* teaches away from the claimed invention and does not, either alone or in combination with any of the cited references, suggest same.

Furthermore, it should be noted that *Yoshida* is totally silent on what kind of intestinal bacteria were used. Therefore, *Yoshida* either alone or in combination with the cited references, does not disclose or suggest the claimed invention.

Nor does *Yaeshima*, when added to the combination of references, disclose or suggest the claimed invention. First, it must be pointed out that *Yaeshima* does not mention lactobacillus but a bacteria species of a non-related gender. In this regard, *Yaeshima* teaches *Bifidobacterium longum* together with lactulose. Further, no gender, but a species-specific effect is described (*B. longum*) only. Perhaps, most importantly, it was found that *B. longum* alone did not lead to a significant increase in calcium absorption but, that lactulose must be present (see Figure 13). In this regard, *Yaeshima* found a lactose-dependent effect on calcium absorption, which once again teaches away from the present invention which discloses and claims a lactobacillus-dependent effect.

Accordingly, none of the prior art references either alone or in combination suggests that living bacteria within the intestines and in the vicinity of the intestinal cells, can help increase the absorption of calcium by the cells. This effect is surprising and contrary to the teaching of the prior art, e.g., *Sellars*, which appears to suggest that the effect is dependent on an acidified medium (dairy product). In contrast to *Sellars*, the present invention teaches that even without a

fermented (acidified) dairy product lactobacilli directly and solely causes the intestinal cells to absorb calcium at a higher rate.

Accordingly, Applicants respectfully submit that the obviousness rejection is not proper and therefore requests that it be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please amend Claims 11, 14, 19 and 23 as follows:

11. (Amended) A method for the treatment or prophylaxis of [treating mineral] calcium deficiencies in a mammal having or at risk of calcium deficiency comprising the steps of enterally administering to the mammal a nutritional composition comprising one or more *Lactobacillus* bacteria.

14. (Amended) The method of Claim 11 wherein the nutritional composition is a liquid and comprises about 10^7 to about 10^{11} cfu/ml of the *Lactobacillus* bacteria.

19. (Amended) A method for increasing absorption of [minerals] calcium from a diet comprising the steps of enterally administering to a mammal requiring increased calcium absorption a nutritional composition comprising one or more *Lactobacillus* bacteria.

23. (Amended) A method for improving the absorption of [minerals] calcium in a mammal comprising the steps of enterally administering to the mammal requiring increased calcium absorption a nutritional composition comprising one or more *Lactobacillus* bacteria.

Please cancel Claims 15 and 20 without prejudice or disclaimer.